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Does a Self-Management Program Change Dietary Intake in Adults With Irritable Bowel Syndrome?

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Making dietary changes such as increasing fiber intake is recommended for the management of irritable bowel syndrome symptoms. Few studies have explored the efficacy of education on compliance with recommendations such as increasing fiber, vegetable, and fruit intake in adults with irritable bowel syndrome. This study examined the effect of a multicomponent self-management intervention that included strategies to enhance fiber, vegetable, and fruit intake. Participants with medically diagnosed irritable bowel syndrome were randomized to usual care or individualized comprehensive self-management, delivered either in-person or by telephone. Since previously published analyses show the two delivery modes to be equally effective, the two intervention groups were combined. Of the 188 individuals randomized, 173 participants (113 in the self-management group and 60 in the usual care group; 23 men, 150 women) provided data on at least one of the three follow-up occasions (3, 6, and 12 months postrandomization). Fiber, vegetable, and fruit intakes were measured using the Food Frequency Questionnaire. Participants in the intervention group demonstrated increases ($p < .05$) in fiber and fruit intake and a trend in vegetable intake at 6 and 12 months postintervention. Improvement in dietary fiber intake following a self-management intervention for IBS continues to 1 year.

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Irritable bowel syndrome (IBS) is a chronic and recurring functional disorder of the gastrointestinal (GI) tract characterized by upper and/or lower abdominal pain relieved by defecation in the absence of organic disease (Camilleri, 2001). It is estimated that IBS affects up to 7%--15% of the population in Western countries, and the prevalence in women is approximately twice that of men (Chang et al., 2006; Clarke, Quigley, Cryan, & Dinan, 2009; Voci & Cramer, 2009). The etiology of IBS remains elusive, but factors such as altered GI motility, increased visceral hypersensitivity, post-infection, altered central nervous system, and autonomic nervous system dysregulation have all been reported as possible causes of GI symptoms in men and women (Clarke et al., 2009; FitzGerald, Kehoe, & Sinha, 2009). Because the etiology of IBS is unknown and GI symptoms are diverse in patients with IBS, the selection of treatment may be challenging for healthcare providers (Reme, Kennedy, Jones, Darnley, & Chalder, 2010).

Background

Studies have demonstrated that patients with IBS benefit from multicomponent self-management programs that include education, stress management, dietary modification, cognitive restructuring, and exercise (Bengtsson, Ulander, Borgdal, & Ohlsson, 2010; Heitkemper et al., 2004; Jarrett et al., 2009). The goal of a self-management program is to facilitate self-care skills and a healthy lifestyle to decrease IBS symptoms and to enhance quality of life. Often, these programs contain diet counseling as part of the intervention (Heitkemper et al., 2004). In a survey of 256 British patients with IBS, approximately 82% of patients responded that they would accept dietary change if prescribed by their healthcare provider (Harris & Roberts, 2008). Recently, we reported that delivering a cognitive behavioral program that includes dietary changes by an advanced practice nurse also has benefit.

As noted in studies of other chronic illness populations, compliance with dietary changes is variable and failure to comply can have deleterious effects. For example, Nachman et al. (2010) found that long-term deterioration of quality of life in patients with celiac disease was associated with noncompliance with a gluten-free diet. Treatment responses are influenced by participant engagement in dietary modifications, attendance at sessions, or type or number of homework assignments.

It has long been hypothesized that certain foods and their constituents could contribute to symptom onset or may play a role in the etiology of IBS (Ducrotte, 2009; Morcos, Dinan, & Quigley, 2009). Inadequate dietary fiber intake is thought to contribute to IBS symptoms, especially constipation; however, the data are limited because of variations in type of fiber and duration of treatment across studies (Grundmann & Yoon, 2010). Regardless, fiber supplementation is often considered as part of a component of behavioral strategies for IBS.

Zuckerman (2006) provided several potential mechanisms by which fiber can play a role in the management of IBS symptoms. For example, dietary fiber hastens oroanal transit time, decreases the whole gut transition time, holds water to prevent excess dehydration of stool, and adds bulk to the stool that may relieve the GI symptom of constipation (Anderson et al., 2009; Friedman, 1991). Dietary fiber also decreases intracolonic pressure either by direct effect or by binding bile salts that can reduce visceral pain caused by colon wall tension (Camilleri, Heading, & Thompson, 2002; Friedman, 1991; Lacy & Lee, 2005; Zuckerman, 2006). Two meta-analyses and four systematic reviews concluded, however, that fiber has only limited or modest effects in patients with constipation-predominant IBS. In addition, insoluble fiber (bran) supplementation has been linked to worsening of IBS symptoms (Bijkerk et al., 2009).

The inconsistencies in the literature related to fiber intake may be related to variations in patient compliance with increasing dietary fiber as well as the strategies used to inform patients about diet changes. The effectiveness of a self-management modification program on behavior change such as increasing the consumption of fiber, vegetables, and fruits remains poorly understood.

On the basis of the data from two randomized clinical trials, we reported that a comprehensive self-management program that includes an individualized dietary component significantly increased quality of life and reduced GI and psychological distress symptoms in patients with IBS as far as 12 months postrandomization (Heitkemper et al., 2004; Jarrett et al., 2009). It is not known, however, what specific component of the intervention (e.g., relaxation training, dietary modification) may have contributed to the overall improvement noted. As such, the current analysis was performed to determine whether dietary changes occurred in those receiving the comprehensive self-management program.

Study Purpose

The purposes of this study were to compare dietary intake of fiber, vegetables, and fruits at baseline and 3, 6, and 12 months postintervention of IBS patients receiving a comprehensive self-management (CSM) program including individualized dietary counseling delivered by telephone or in person to usual care (UC). We hypothesized that participants in the self-management groups would report significantly greater change in dietary fiber, vegetable, and fruit intake at the 3- and 6-month follow-ups as compared to the UC group.

Methods

Design

A three-arm, randomized, controlled trial design was used to test the efficacy of a CSM intervention delivered primarily by telephone (CSM-T/IP) or entirely in person (CSM-IP) compared to UC. As part of the intervention, participants were encouraged to increase their fiber intake. All three groups completed interviews, questionnaires including a Food Frequency Questionnaire (FFQ), and kept a symptom diary for primary and secondary outcomes at each of four assessment periods (baseline, 3, 6, and 12 month postrandomization). Results from this study have been previously reported for the outcomes of IBS symptoms, psychological distress, and quality of life (Jarrett et al., 2009).

Sample

Adults with IBS were recruited through community advertisements and direct mailings for a gastroenterology clinic. Potential participants were screened over the telephone to confirm study eligibility. All participants were 18 to 70 years old. Those in the IBS group had to have a diagnosis of IBS made by a healthcare provider (e.g., internist, gastroenterologist, or nurse practitioner) and experiencing IBS symptoms as defined by the Rome II criteria. This criterion requires self-reported abdominal discomfort or pain for at least 12 weeks that is associated with two of three features: (1) relieved by defecation, (2) onset associated with a change in stool frequency, and (3) onset associated with a change in stool form. In addition, participants had to have supporting features of IBS (i.e., 25% of the time having constipation or diarrhea symptoms or both).

To avoid potential confounders that might influence the outcome, potential participants were excluded if they had a history of GI pathology (e.g., inflammatory bowel disease), GI surgery (e.g., bowel resection but not appendectomy), and renal or gynecologic pathology (e.g., women with endometriosis or men with prostate cancer) that might cause IBS-like symptoms. Moreover, if potential participants took specific medications (e.g., antibiotics,

anticholinergics, cholestyramine, narcotics, colchicine, docusate, enema preparations, and laxatives other than fiber) three or more times a week, they were excluded from participating.

Measures

Demographics—Participants self-reported their age (in years), gender (female or male), employment status (full-time or part-time work or retired), and formal education level (12th grade or General Educational Development, or at least a college degree).

Dietary Intake—The self-reported FFQ was used to measure the type and quantity of food intake (Kristal, Feng, Coates, Oberman, & George, 1997). Participants completed the FFQ at baseline, 3 months, and 6 months. In Part 1 of the FFQ, participants recorded the information on the frequency of consuming vitamin and mineral supplements and the use of fats. In Part 2 of the FFQ, participants rated the serving size (small, medium, or large) and the frequencies of usual food intake, including (a) cereals, bread, and snacks; (b) meat, fish, and eggs; (c) spaghetti, mixed dishes, and soups; (d) dairy products; (e) vegetables and grains; (f) sauces and condiments; (g) fruits; (h) sweets; and (i) beverages and alcohol. Frequency is based on a 9-point scale with the range from *never or less than once per month* to *2+ times per day*.

The reliability of the FFQ was established by the National Health and Nutrition Examination Survey (NHANES II) (Gibson, 1990; Hu et al., 1999). In the Women's Health Initiative study, the test-retest reliability of the nutrient intake estimates from the FFQ was reported as high. Intraclass correlation coefficients ranged from 0.67 to 0.92 (Patterson et al., 1999).

Protocol

This study was approved by the University of Washington institutional review board. After providing informed consent, all study participants were interviewed individually. Two trained research nurses conducted the interviews to minimize variation. Participants were taught how to monitor and record their symptoms. After the baseline assessment, participants were randomly assigned using a customized computer program to the CSM-T/IP, CSM-IP, or UC group (Jarrett et al., 2009).

As part of the intervention, the dietary modification strategies was based on the American Dietetics Association (ADA) recommendations for fiber intake (ADA, 2008) and the Food Guide Pyramid for vegetable and fruit intake (Centers for Disease Control and Prevention, 2010; U. S. Department of Agriculture, 2010). The fiber intake recommendations were individualized on the basis of the symptoms (e.g., constipation, diarrhea). The research nurse set the goal of 25 grams of fiber per day in constipation-predominant IBS patients and 20 grams of fiber for diarrhea-predominant IBS patients. Participants in alternating or mixed IBS subgroups received recommendations adjusting fiber intake based on the predominant symptom (diarrhea or constipation).

Goals for fiber intake were met by completing a daily food record for 1 week and slowly increasing the amount of dietary fiber across thenine sessions. An *IBS Workbook* was used throughout the intervention to complement the sessions with additional information and examples of high fiber foods. Participants in the UC group did not receive the *IBS Workbook* until they finished the study.

Statistical Analysis

Fiber intake per day is the primary outcome measure, but four other measures relevant to fiber intake are also reported: (1) water-soluble fiber intake per day, (2) water-insoluble

fiber intake per day, (3) servings of fruit per day, and (4) servings of vegetables per day. Change scores from baseline to each follow-up time are computed, and mean and standard deviation (*SD*) of change scores are reported. Calories per day were also examined as a possible confounder.

The primary aim of this article is to test whether participants receiving CSM had a larger increase in fiber intake than those receiving UC. There were no significant differences between the two CSM groups, in-person versus telephone, on any of the outcome measures; therefore, the two CSM groups were combined for all analyses.

A mixed model analysis of covariance is used for the primary analysis. The model contains treatment group (CSM vs. UC) and follow-up occasions (3, 6, 12 months postrandomization) as fixed factors, subject number as a random factor, and baseline value of the outcome variable as a covariate. The outcome is change from baseline to each follow-up time in fiber intake, or one of the other outcomes. The coefficient on treatment group measures how much the CSM group differs from the UC group at the three follow-up times, on average, and the corresponding *p*-value tests whether this difference is statistically significant. In addition, separate analyses are done for each follow-up time point (3, 6, and 12 months postrandomization) using analysis of covariance.

Because an initial analysis shows that change in fiber intake per day is highly correlated with change in calories per day, additional analyses were performed which control for baseline and change score of calories per day. To test whether treatment effectiveness differed by predominant bowel pattern, mixed model analyses were done, which included predominant bowel pattern (constipation predominant, diarrhea predominant, or mixed) and an interaction between treatment group and predominant bowel pattern.

Initial examination of the data revealed two extreme outliers, both at 12-month follow-up. One subject had a computed value of 17 for calories per day; another had 8,200 calories per day. These two observations were excluded from analysis; the first is almost certainly erroneous data, the second may be accurate data but is so extreme that it would have a disproportionate impact on analyses. This subject had reasonable caloric intake on the three other occasions (2,000--3,500), so this occasion was even extreme for this subject. The next largest caloric intake was 5,400 for a subject whose caloric intake was about 4,000 on the other three occasions.

Results

There were 188 subjects randomized. Of these, 173 participants (113 in the self-management group and 60 in the UC group; 23 men and 150 women) provided outcome data on at least one of the three follow-up occasions (3, 6, and 12 months postrandomization).

Demographic characteristics and predominant bowel pattern at baseline are displayed in Table 1. The only factor on which the UC and CSM groups differ is education, with a higher fraction of the CSM group having a college education.

Table 2 shows means and *SDs* of the outcome variables at baseline, and the change from baseline to follow-up at each of the three follow-up times. At baseline, fiber intake was somewhat higher in the UC than in the CSM group ($p = .042, .034, \text{ and } .051$ for total, soluble, and insoluble fiber, respectively). This chance imbalance in randomization was accounted for by including baseline value of the outcome variable in all analyses. As seen in the last row of Table 2, calories per day decreased somewhat more in the UC group than in the CSM group.

Fiber intake decreased from baseline to follow-up in the UC group, but increased in the CSM group ($p = .007$). Controlling for baseline calories and change in calories per day decreased the significance ($p = .024$). Among the secondary outcomes, the biggest effect of CSM was on insoluble fiber and fruit servings per day, with lesser nonsignificant effects on soluble fiber and vegetable servings per day.

There were no significant bowel pattern subgroup differences at baseline. There were no significant treatment by bowel pattern group interactions, meaning there was no evidence that the impact of CSM on fiber intake differed by predominant bowel pattern subgroup.

Discussion

Comprehensive approaches to symptom management in patients with IBS frequently include dietary modifications such as increasing dietary fiber (soluble and insoluble) and avoiding lactose and gas producing foods. This study examined the effectiveness of a nurse-delivered CSM program that included individualized dietary recommendations on increasing dietary intake of fiber, vegetables, and fruits in patients with IBS. The results support the hypothesis that IBS patients in the self-management program substantially alter their dietary intake of fiber and fruits for at least 12 months following the intervention.

Overall, the results of this study are consistent with those of Monsbakken, Vandvik, and Farup (2005), who found that 64% of participants with IBS ($n = 65$) who received individualized dietary advice complied with dietary recommendation for increasing fiber intake for at least 6 months. The results of this study indicate that the effects of an individualized approach can be sustained for at least 12 months. In the study of Monsbakken et al. (2005), those individuals with psychological comorbidity responded less well in terms of GI symptom relief compared with those without comorbidities. These results are somewhat different than studies of patients with other chronic health problems.

For example, in a study of patients with coronary heart disease, Hamalainen et al. (2000) found that participants relapsed to inadequate dietary intake at the 6-month follow-up period after receiving a 2-week intensive low-fat diet counseling intervention. Twardella et al. (2006) also performed a prospective study in patients with heart disease and suggested that patients can make dietary changes in the short term, but dietary changes are hard to maintain for the long run; participants often relapse to their previous dietary habits. For patients with IBS, dietary changes may be accompanied by relief of symptoms or increased sense of control of symptoms, which may provide positive feedback for sustaining dietary changes.

It is important to point out that the levels of dietary fiber intake in this group of patients with IBS are higher than that noted in other studies of women with IBS or chronic GI symptoms. In 1994, Georges and Heitkemper reported that the average fiber intake of 20 midlife women with IBS was 9.02 grams per day based on nine daily diet diaries over a 1-month period (Georges & Heitkemper, 1994). In a subsequent study of premenopausal women using 3-day food records, however, we found that women with GI symptoms had higher fiber intake than that noted in postmenopausal women, and only marginally less than women without symptoms (13.3 ± 2.4 grams per day vs. 14.6 ± 1.1 grams per day of fiber) (Jarrett, Heitkemper, Bond, & Georges, 1994). The higher levels of fiber intake among women with IBS in the current study may be related to increased awareness of the value of fiber (e.g., lowering blood cholesterol and glucose levels) (Craig & Mangels, 2009; Ferdowsian & Barnard, 2009) as well as its potential benefit for GI symptoms such as constipation (Anderson et al., 2009).

At baseline, the fiber intake found in this group of patients with IBS is similar to the general population in the United States (Thompson et al., 2005; Wolk et al., 1999). The 2000

National Health Interview Survey found that the mean dietary fiber intake was 19.2 grams per day for men and 14.4 grams per day for women (Thompson et al., 2005). Both IBS patients as well as the general population, however, consume less than the recommended daily amount of fiber (25--30 gm) (ADA, 2008).

One goal of *Healthy People 2010* is to reduce chronic disease risk through healthy diet recommendations. *Healthy People 2010* recommends 3 to 5 servings of vegetables and 2 to 3 servings of fruit per day (U.S. Department of Health and Human Services, 2000). At baseline, mean vegetable and fruit intakes of the sample were lower than the recommended intakes. In a recent report from the Centers for Disease Control and Prevention, it was shared that as of 2009, no U.S. state had met target recommendations for either vegetable or fruit intake.

Again, the consumption of vegetables and fruits for these IBS patients was similar to that found in studies of the general population. For example, in a study of midlife and older rural women, Pullen and Walker (2002) noted that the average levels of consumed vegetables and fruits were 2.63 servings and 2.0 servings per day, respectively. Fruit and vegetable intakes are influenced by a number of factors including culture, availability, and cost. In a study of IBS patients using the 72-hour dietary recall in India (Malhotra, Rana, Sinha, & Khurana, 2004), intake of vegetables and fruits in patients with IBS was lower than that in healthy control subjects. This discrepancy between these findings and the current study may be due to data collection strategy (i.e., FFQ vs. 72-hour recall) as well as cultural influences.

In the current study, the CSM intervention reduced GI symptom reports and enhanced quality of life (Jarrett et al., 2009). The current analysis suggests that this may have been due to the individualized dietary alterations. Many patients with IBS, including those in the current study, noted that food precipitates or aggravates their symptoms (Jarrett, Visser, & Heitkemper, 2001); however, few studies have demonstrated a sustained effect of dietary interventions (Pare et al., 2007; Spiller et al., 2007). In this study, individualized dietary recommendations were delivered to intervention groups and were intended to educate participants on how to gradually increase their fiber intake via fruit and vegetable intake. Participants were instructed based on their self-reported GI symptoms to ultimately achieve the recommended levels. It was hypothesized that those in the treatment groups would increase fiber as well as vegetables and fruit intake over time, while those in the UC group would not. In both interventions groups, there was an increase in fiber and fruit, but not vegetables. This may have been related to the ease of fruit intake (e.g., banana, apple).

Despite the sporadic pattern of IBS symptom occurrence, patients were able to increase their dietary intake of both soluble and insoluble fiber as well as fruit. The majority of participants were women with IBS. In a population-based cross-sectional study, Faresjo, Johansson, Faresjo, Roos, and Hallert (2010) examined gender differences in dietary coping with GI symptoms. Women with IBS seemed more willing to change dietary habits because of their symptoms than men. In that study, fatty foods, certain vegetables, dairy products, and eggs were more likely to be reported as the cause of GI complaints among IBS patients compared with their controls without IBS. The relatively small number of men in the current study does not allow for meaningful gender comparisons.

The results of the current study need to be cautiously interpreted. In the CSM program, participants were asked to identify specific foods that they believed contributed to their symptoms. The nurse counselor then worked with the patients as part of the intervention to develop strategies for how and when to avoid such foods if possible. Thus, the improvement in GI symptoms found in the current study may be related to these additional dietary strategies and/or the reduction in self-report of stress noted by many of the patients. In

addition, social desirability bias is also an important construct when examining dietary intake measures, and it was not measured in the current study. Miller and colleagues studying healthy women demonstrated that both the FFQ as well as a limited diet recall measure of fruit and vegetable intake are susceptible to substantial approval bias (Miller, Abdel-Maksoud, Crane, Marcus, & Byers, 2008).

There were no IBS bowel pattern subgroup differences in response to treatment. Studies have confirmed that there is a beneficial effect in increasing fiber intake for constipation-predominant IBS patients (Arffmann et al., 1985; Cann, Read, & Holdsworth, 1984; Kruis, Weinzierl, Schussler, & Holl, 1986; Kumar, Kumar, Vij, Sarin, & Anand, 1987; Lambert et al., 1991; Manning, Heaton, & Harvey, 1977; Prior & Whorwell, 1987); however, the data regarding the efficacy of increasing fiber intake for diarrhea-predominant or mixed IBS patients are still inconsistent.

Currently there are no dietary recommendations for diarrhea-predominant IBS patients by the American Gastroenterological Association. Participants often relate their symptoms to specific food items such as carbohydrates and fat (Monsbakken et al., 2005; Simren et al., 2001). Floch and Narayan (2002) indicated that the symptoms of diarrhea might be caused by food intolerances; however, in a large data-based study, Saito, Locke, Weaver, Zinsmeister, and Talley (2005) found no differences in “culprit” foods including wheat-, lactose-, caffeine-, and fructose-containing foods between those with and without functional GI disorders.

The assessment of compliance with dietary recommendations is challenging when conducting a clinical trial aimed at changing dietary intake. Methodological issues include the format of the assessment tool used. In this study, the measurement of compliance was based on a self-report FFQ. It has been noted that FFQs harbor systematic errors according to participants’ age, gender, and body mass index, as well as random errors (Dahm et al., 2010). Additional measures include prospective food diaries, which show better correlation with biomarkers of nutrient intake; however, analysis of food diaries is expensive and adds to subject burden.

Conclusions

Dietary change is one strategy employed in the treatment of patients with IBS. For the healthcare provider, the findings of our study suggest that the consumptions of fiber are lower than those recommended in patients with IBS, and dietary change behaviors are difficult to sustain. This information identifies the need for dietary interventions for improving compliance with dietary modifications in patients with IBS. In the future, dietary modification interventions could take into account the processes of dietary change to avoid relapses.

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TABLE 1

Baseline Demographic Characteristics and Predominant Bowel Pattern by Treatment Groups in Adults With Irritable Bowel Syndrome

Variable	UC Group (n = 60)	CSM Group (n = 113)	p
Age (M ± SD)	43 ± 14	45 ± 14	ns
Gender, female, n (%)	51 (85)	99 (88)	ns
Married or partner, n (%)	28 (47)	52 (46)	ns
College or graduate, n (%)	34 (57)	81 (72)	.035
Employment status, n (%)			
Retired	7 (12)	13 (12)	ns
Full-time	26 (43)	52 (46)	
Part-time	18 (30)	29 (26)	
Other	9 (15)	19 (17)	
Predominant bowel pattern, ^a n (%)			
Normal	2 (3)	7 (6)	ns
Constipation	11 (18)	28 (25)	
Diarrhea	31 (52)	60 (53)	
Alternating	16 (27)	18 (16)	

Note. P value tests the group differences using one-way analysis of variance for continuous variable (age) or Pearson χ^2 for categorical data. UC = usual care; CSM = comprehensive self-management.

^aPredominant bowel pattern based on Rome II criteria (Adapted from *Rome II: The Functional Gastrointestinal Disorders* by D. A. Drossman, E. Corazziari, N. J. Talley, W. G. Thompson, & W. E. Whitehead, 2000, 2nd ed., Lawrence, KS: Allen Press, Inc.

TABLE 2
Mean and Standard Deviation (SD) of Baseline and Change Scores of Dietary Intake Variables by Intervention Group

Variable	N	Baseline	N	Change to 3 Months	N	Change to 6 Months	N	Change to 12 Months	<i>p</i> ^d
Total fiber (g/day)									
UC	60	20.5 (8.4)	57	-1.4 (6.7)	55	-3.4 (7.2)	54	-3.5 (8.5)	.007/.024
CSM	113	17.8 (8.0)	108	1.3 (6.6)	105	0.4 (6.4)	104	0.9 (8.6)	
		<i>p</i> ^b		.061/.157		.008/.022		.020/.255	
Soluble fiber (g/day)									
UC	60	5.3 (2.4)	57	-0.3 (2.1)	55	-0.9 (2.3)	54	-0.9 (2.5)	.069/.372
CSM	113	4.6 (2.0)	108	0.3 (1.6)	105	0.0 (1.6)	104	0.2 (2.3)	
		<i>p</i> ^b		.331/.999		.076/.314		.036/.466	
Insoluble fiber (g/day)									
UC	60	15.1 (6.1)	57	-1.2 (4.8)	55	-2.6 (5.1)	54	-2.5 (6.2)	.003/.013
CSM	113	13.2 (6.0)	108	1.1 (5.0)	105	0.4 (4.9)	104	0.7 (6.4)	
		<i>p</i> ^b		.035/.087		.004/.010		.020/.238	
Fruits/day									
UC	60	2.0 (1.4)	57	0.0 (1.6)	54	-0.5 (1.4)	54	-0.3 (1.3)	<.001/.002
CSM	112	1.8 (1.3)	108	0.5 (1.5)	103	0.3 (1.3)	101	0.4 (1.5)	
		<i>p</i> ^b		.048/.129		.001/.002		.006/.066	
Vegetables/day									
UC	60	2.6 (1.7)	57	0.1 (1.6)	54	-0.3 (1.6)	54	-0.1 (1.3)	.177/.401
CSM	112	2.4 (1.4)	108	0.2 (1.5)	103	0.2 (1.5)	101	0.3 (1.4)	
		<i>p</i> ^b		.855/.812		.112/.137		.130/.374	
Calories/day									
UC	60	1692 (670)	57	-104 (510)	55	-274 (629)	55	-299 (604)	.049/-----
CSM	113	1600 (595)	108	37 (527)	105	-113 (512)	104	-64 (598)	
		<i>p</i> ^b		.146/-----		.217/-----		.025/-----	

Note. UC = usual care; CSM = comprehensive self-management.

^a *P* values are from mixed model analysis of covariance, using all three follow-up times to test the effect of CSM; first *p* value controls for baseline of the outcome and second *p* value also controls for baseline and change in calories/day.

^b *P* values are from analyses of covariance that test the effect of CSM at each time point; first *p* value controls for baseline of the outcome and second *p* value also controls for baseline and change in calories/day. [Two outliers are removed]